Remarks

Claims 1-5 and 9-23 are pending in this application. Claims 6-8 and 24-33 were cancelled in a preliminary amendment filed on July 20, 2006. Claims 12-23 have been withdrawn from consideration in response to a restriction requirement. Accordingly, claims 1-5 and 9-11 are subject to examination.

Claims 1, 2, 5 and 9-11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pontier, et al., "About the use of stoichiometric hydroxyapatite in compression - incidence of manufacturing process on compressibility", May 2001.

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Itoh et al., "A New Porous Hydroxyapatite Ceramic Prepared by Cold Isostatic Pressing and Sintering Synthesized Flaky Powder", Dental Materials Journal, 13(1):25-35 (1994).

Paragraphs [0176], [0198], [0200], [0203] and [0210] are amended to indicate registered trademarks. Paragraph [0198] has also been amended to provide the generic description of the Chilsonator® device as a "roller/compactor system". No new matter is added.

Claim 1 has been amended to recite that the hydroxyapatite particles have a particle size such that 90% of the particles have a particle size smaller than 260 microns. This amendment is supported in the specification at, for example, paragraph [0084] of the specification. No new matter is added.

As described in the application and recited in the claims as amended, the present invention is directed to a calcium phosphate hydroxyapatite having a specific, controlled particle size range. The controlled particle size of the hydroxyapatite is a result of the process by which

the calcium phosphate hydroxyapatite has been formed. By controlling the particle size distribution of the starting brushite material, a calcium phosphate hydroxyapatite can be formed directly having a particle size distribution in a range that that has good flow and compressibility characteristics. The direct formation of calcium phosphate hydroxyapatite in the desired particle size allows the user to forego processing steps to granulate the hydroxyapatite formed by prior methods.

To anticipate a claim under Section 102(b), a single prior art reference must disclose each and every element set forth in the claim. Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14 (Fed. Cir. 2000); Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. Because neither Pontier nor Itoh disclose hydroxyapatite having the particle size distribution recited in claim 1 as amended, the claims are not anticipated by Pontier or Itoh.

Pontier, et al., "About the use of stoichiometric hydroxyapatite in compression - incidence of manufacturing process on compressibility", May 2001, describes a study that was performed to determine the effect of the Ca/P molar ratio in hydroxyapatite on compressibility. The method of synthesis of the hydroxyapatite used in the study is described in Section 2.1 of Pontier. Pontier describes formation of hydroxyapatite by precipitation by combining diammonium phosphate and calcium nitrate at a pH of 9.5 and temperature of 95°C. Precipitates were maintained at room temperature for 7 days to allow the hydroxyapatite to reach the desired Ca/P molar ratio. The resulting hydroxyapatite was dried, filtered and granulated to obtain hydroxyapatite granules having mean diameters of either 200 microns or 400 microns.

In Figure 4 of Pontier, a graph showing the cumulative percentage of material retained on screens of various sizes for the granulated hydroxyapatite powders described by Pontier. Although there is no data point provided at 300 microns, the Examiner has stated that the graph shows that 90% of the granulated hydroxyapatite has a particle size smaller than 300 microns. Claim 1 has been amended to recite that the hydroxyapatite of the present invention has a particle size such that 90% of the hydroxyapatite has a particle size smaller than 260 microns. Figure 4 of Pontier shows that the granulated hydroxyapatite does not meet this limitation, as about 30% of the hydroxyapatite particles of Pontier are greater than 260 microns (i.e. about 70% are less than 260 microns). Accordingly, Pontier does not anticipate claim 1 as amended for at least this reason. Moreover, Pontier does not anticipate claims 2-5 and 9-11, which depend from claim 1, for at least the same reason.

Itoh et al., "A New Porous Hydroxyapatite Ceramic Prepared by Cold Isostatic Pressing and Sintering Synthesized Flaky Powder", Dental Materials Journal, 13(1):25-35 (1994) describes a hydroxyapatite powder synthesized using a two step method to obtain calcium phosphate hydroxyapatite having a stoichiometric amount of calcium and phosphate. The Examiner states at page 4 of the Office Action that Itoh describes a mean particle size of 200 microns. This is not correct. Itoh describes the resulting hydroxyapatite powder as having a particle size "distributed in the range of 1-80 μm and the mean particle size was determined to be about 15 μm..." Itoh, page 27. In order for the mean particle size to be 15 microns, more than 10% of the hydroxyapatite of Itoh must be less than 10 microns (i.e. less than 90% are greater than 10 microns). While Itoh describes forming larger granules from the hydroxyapatite powder, these granules were 300 to 500 microns in diameter. Itoh, page 27. Itoh does not describe a hydroxyapatite product having the particle size distribution recited in claim 1 as amended.

Accordingly, Itoh does not anticipate claim 1, or dependent claims 2-5 and 9-11, for at least this reason.

In view of the amendments to the claims and the foregoing remarks, the pending claims are believed to be allowable over the prior art of record. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicants' attorney would be advantageous to the disposition of this case, Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

A Petition for a Two Month Extension of Time along with the associated fees are filed herewith. No additional fee is believed to be required. In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

Dated: July 6, 2009

Respectfully submitted,

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